UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,439	11/04/2003	Christopher Burgess	1657/2022	5656

29932 7590 05/14/2007

SONNENSCHEIN NATH & ROSENTHAL LLP
FOR PAULA EVANS
P.O. BOX 061080
WACKER DRIVE STATION, SEARS TOWER
CHICAGO, IL 60606-1080

EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
05/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,439	BURGESS ET AL.	
	Examiner	Art Unit	
	Scott D. Long	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 8-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Examiner acknowledges the election, with traverse, of Group I-B directed to a method of detecting cancer using SEQ ID NO:1, in the reply filed on 28 February 2007.

Because no argument for the traversal was provided by applicant, thus the traversal is non-persuasive and the restriction is made final.

Claim Status

Claims 1-33 are pending. However, claims 1-5 and 8-33 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 6-7 are under current examination.

Sequence Compliance

Sequence Listing and CRF have been received and are acknowledged by examiner. A statement that the Computer Readable Form (CRF) and the Sequence Listing are identical has been submitted and is acknowledged by examiner.

Oath/Declaration

The oath or declaration, having the signatures of all inventors, received on 27 February 2004 is in compliance with 37 CFR 1.63.

Information Disclosure Statement

The Information Disclosure Statements (IDS) filed on 6 February 2004 consisting of 2 sheets are in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements. The examiner wishes to thank the applicant for the courtesy of drawing the examiner's attention to several pending applications with shared assignment to Bayer.

Priority

The instant application has been granted the benefit date, 11 April 2003, from the filing date of the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of detecting breast cancer by comparing expression levels of SEQ ID NO:1 in the biological sample of a subject to the expression levels of SEQ ID NO:1 in a control sample, does not reasonably provide enablement for methods of detecting any cancer or pre-malignant condition thereof by comparing expression levels of SEQ ID NO:1 in a biological sample of a subject and

control sample. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some 'experimentation.'" Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

SCOPE OF THE INVENTION

The breadth of the claims encompasses methods of detecting a genus of cancers or pre-malignant conditions thereof, by comparing expression levels of SEQ ID NO:1. As discussed supra, the specification fails to describe the method of detecting a

genus of cancers using SEQ ID NO:1 and would require undue experimentation to discover these cancer types associated with SEQ ID NO:1.

GUIDANCE & WORKING EXAMPLES

The specification does not provide specific guidance for or a working example for detecting any particular cancer using any particular SEQ ID NO, even though the elected group is drawn to methods of detecting cancer associates with expression levels of SEQ ID NO:1. The specification lists numerous examples of cancer: "squamous cell cancer, small-cell lung cancer, non-small cell lung cancer, gastrointestinal cancer, Hodgkin's and non-Hodgkin's lymphoma, pancreatic cancer, glioblastoma, cervical cancer, ovarian cancer, liver cancer such as hepatic carcinoma and hepatoma, bladder cancer, breast cancer, colon cancer, colorectal cancer, endometrial, carcinoma, salivary gland carcinoma, kidney cancer such as renal cell carcinoma and Wilms' tumors, basal cell carcinoma, melanoma, prostate cancer, vulva1 cancer, thyroid cancer, testicular cancer, esophageal cancer, and various types of head and neck cancer. Preferably, the cancers include breast, colon, and lung cancer." (page 56, lines 10-21). The specification also describes the method for detecting cancer by detecting "disclosed cancer-specific markers (i.e., the nucleic acid sequences of one or more nucleic acid sequences encoding the cancer specific marker...the marker sequences are the ones comprising a nucleic acid sequence selected from the group consisting of SEQ ID NOS: 1-93." (page 56, lines 6-7 and 19-21). The absence of working examples specifically directed to methods of detecting any cancer using SEQ

ID NO:1 necessitates further experimentation. Therefore, the specification does not provide sufficient guidance on how to use expression levels of SEQ ID NO:1 to identify the large number of types of cancer.

STATE OF THE ART & QUANTITY OF EXPERIMENTATION

In fact, the state of the art teaches that SEQ ID NO:1 is a breast cancer marker gene. Su et al. (US application - US20040005644A1) teach, "method for detecting breast cancer in a subject, said method comprising the steps of: (a) determining a level of a transcribed polynucleotide in a biological sample from said subject, wherein said transcribed polynucleotide comprises a nucleic acid sequence recited in any one of SEQ ID NOS:1-19, or a complement of any of the foregoing nucleic acid sequences; (b) comparing the level of said transcribed polynucleotide in said biological sample to a control level of said transcribed polynucleotide; and (c) producing a diagnosis based on a result from step (b)." (claim 6, page 87). Su et al. further teach "the term 'breast cancer specific gene (BCSG)' refers to a gene that is over-expressed by at least two-fold (i.e. 200% of normal) or under-expressed by at least two-fold (i.e. 200% of normal) in breast cancer tissue or cell lines relative to normal tissue or cell lines." (page 3, paragraph 0026) Su et al. also teach SEQ ID NO:6 which is a 2163 bp polynucleotide sequence that is 100% identical to SEQ ID NO:1 of the instant application.

Although many marker genes for a specific type of cancer, may also be present in other types of cancer, there is nothing in the specification that indicates that SEQ ID NO:1 is specific for any type of cancer. Therefore it would require undue

experimentation for a skilled artisan to practice the invention as a method for detecting any type of cancer using expression levels of SEQ ID NO:1.

CONCLUSION

In conclusion, given the breadth of the claims and the limited scope of the specification, an undue quantity of experimentation is require to make and use the invention beyond the scope of a method of detecting breast cancer in a subject comprising comparing a) the expression level of nucleic acid sequence SEQ ID NO:1 in a biological sample from the subject with b) a control expression level of said nucleic acid sequence, wherein a change of at least two-fold in the expression level of said nucleic acid sequences is indicative of cancer.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 6-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Su et al (US application - US20040005644A1).

Claim 6 is directed to a method of detecting cancer or a pre-malignant condition thereof in a subject comprising comparing a) the expression level of one or more nucleic acid sequences in a biological sample from the subject with b) a control expression level of said nucleic acid sequences, said nucleic acid sequences comprising one or more nucleic acid sequences selected from the group consisting of SEQ ID NOs: 1, wherein a change of at least two-fold in the expression level of said nucleic acid sequences is indicative of cancer or pre-malignant condition. Claim 7 is directed to the method of claim 6, wherein said change in the expression level is either an increase or decrease in the expression level.

Su et al. teach, "method for detecting breast cancer in a subject, said method comprising the steps of: (a) determining a level of a transcribed polynucleotide in a biological sample from said subject, wherein said transcribed polynucleotide comprises a nucleic acid sequence recited in any one of SEQ ID NOS:1-19, or a complement of any of the foregoing nucleic acid sequences; (b) comparing the level of said transcribed polynucleotide in said biological sample to a control level of said transcribed polynucleotide; and (c) producing a diagnosis based on a result from step (b)." (claim 6,

page 87). Su et al. further teach "the term 'breast cancer specific gene (BCSG)' refers to a gene that is over-expressed by at least two-fold (i.e. 200% of normal) or under-expressed by at least two-fold (i.e. 200% of normal) in breast cancer tissue or cell lines relative to normal tissue or cell lines." (page 3, paragraph 0026) Su et al. also teach SEQ ID NO:6 which is a 2163 bp polynucleotide sequence that is 100% identical to SEQ ID NO:1 of the instant application.

Accordingly, Su et al. anticipated the instant claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-7 are provisionally rejected on the ground of nonstatutory double patenting over claim 31 of copending Application No. 09/328111. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claim 31 of application 09/328111 appears to be a species of a method of detecting cancer using expression profiling of cancer genes, as claimed in the instant application.

Claims 6-7 are provisionally rejected on the ground of nonstatutory double patenting over claim 19-20 and 31-32 of copending Application No. 09/879536. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claims 19-20 and 31-32 of application 09/879536 appears to be a similar of a method of detecting cancer using expression profiling of cancer genes, as claimed in the instant application.

Claims 6-7 are provisionally rejected on the ground of nonstatutory double patenting over claim 18-20 and 31-32 of copending Application No. 09/871161. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claims 18-20 and 31-32 of application 09/871161 appears to be a similar of a method of detecting cancer using expression profiling of cancer genes, as claimed in the instant application.

Claims 6-7 are provisionally rejected on the ground of nonstatutory double patenting over claim 1-2 of copending Application No. 10/610049. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claims 1-2 of application 10/610049 appears to be a similar of a method of detecting cancer using expression profiling of cancer genes, as claimed in the instant application.

Conclusion

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long
Patent Examiner
Art Unit 1633

JANET L. EPPS-FORD, PH.D.
PRIMARY EXAMINER